

Appln. No. 09/241,595  
Amd. dated November 5, 2003  
Reply to Office Action of May 6, 2003

REMARKS

The Office Action and the cited and applied reference have been carefully studied. No claim is allowed. Claims 1, 3-11, and 13-35 presently appear in this application and define patentable subject matter warranting their allowance. Reconsideration and allowance are hereby respectfully solicited.

The rejection of pending claims 1, 3-11, and 13-31 under 35 U.S.C. §112, first paragraph, for lack of enablement is maintained in part. The examiner stated that amendment of the claims to include the language "by an effective route" would be acceptable to overcome this rejection provided that applicant can point to support in the specification for this language. This rejection is respectfully traversed.

The language "by an effective route" is not explicitly supported in the specification as filed but rather is implicit from the teachings therein. The crux of the invention does not lie in the route of administration but rather in the inherent ability of the presentation of antigens according to the present invention to enhance a CTL response. However, for reasons of business strategy and for purposes of advancing prosecution, applicants have amended the claims to recite "administering to said subject by injection into the body of said subject, as

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supported in the specification on page 11, lines 28-30, thereby obviating this rejection.

Reconsideration and withdrawal of the rejection are therefore respectfully requested.

Claims 1, 5-6, 11, 17-18, 25-27, and 29-30 have been rejected under 35 U.S.C. §102(b) as being anticipated by Neurath, U.S. Patent No. 5,039,522. This rejection is respectfully traversed.

Claim 1 is now amended to recite "a biologically active" molecule instead of "an antigenic" molecule, as supported in the specification on page 6, lines 16-18, and claims 1, 11, 17, and 31 are amended to recite that the "biologically active", "immunostimulating", or "antigenic" molecule is not covertly modified, as supported in the specification on page 7, lines 24-25.

The examiner has indicated that in Neurath, the peptide is myristylated, in other words, covalently bonded (covalently modified) to a myristal group, and the absorption of the myristylated peptide to the HBsAg particle is by a non-covalent interaction. However, as presently amended, the claims recite the feature that the biologically active, immunostimulating, and

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antigenic molecules are not covalently modified. Accordingly, the present invention cannot be anticipated by Neurath.

Furthermore, the present invention is specifically directed to enhancing a CTL response. By contrast, it is clear that Neurath is directed to eliciting a humoral response. See column 1, lines 47-51, where it is disclosed that protective antibodies are elicited, and column 10, lines 3-6, where it is disclosed that subsequent doses or the booster depends on the level of antibody in the blood as a result of initial immunization. Accordingly, Neurath cannot anticipate the presently claimed method for stimulating or enhancing a CTL response.

Reconsideration and withdrawal of the rejection are therefore respectfully requested.

A copy of the publication, G. O. Aspinall, Advances in Carbohydrate Chemistry and Biochemistry 51:169-242 (1995), which was inadvertently omitted from the Information Disclosure Statement filed August 28, 2003, is attached hereto along with a PTO-1449 form for the examiner's consideration. This Aspinall reference is a general background reference on variable surface glycolipids of mycobacteria and is not believed to be material to the patentability of the present invention.

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In view of the above, the claims comply with 35 U.S.C. §112 and define patentable subject matter warranting their allowance. Favorable consideration and early allowance are earnestly urged.

Respectfully submitted,

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